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<b>(21) International Application Number:</b> PCT/FI98/00605 <b>(22) International Filing Date:</b> 24 July 1998 (24.07.98) <b>(30) Priority Data:</b> 973108 25 July 1997 (25.07.97) FI <b>(71) Applicants (for all designated States except US):</b> OY BORAGO AB [FI/FI]; Kuusiniementie 6 A 3, FIN-00340 Helsinki (FI). ORIOLA, OY [FI/FI]; Orionintie 5, FIN-02200 Espoo (FI). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> MÄKELÄ, Helena [FI/FI]; Kuusiniementie 6 A 3, FIN-00340 Helsinki (FI). KAURALA, Marita [FI/FI]; Krattivuorentie 12 J 19, FIN-02320 Espoo (FI). RAUTIO, Pia [FI/FI]; Siikalantie 51, FIN-03600 Karkkila (FI). <b>(74) Agent:</b> BERGGREN OY AB; P.O. Box 16, FIN-00101 Helsinki (FI).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>In English translation (filed in Finnish).</i>
<b>(54) Title:</b> FUNCTIONAL FOOD PREPARATE  <b>(57) Abstract</b>  The invention relates to a food preparation comprising a vegetal substance containing phyto-oestrogen, consisting of crushed flaxseed containing lignan and soya flour containing isoflavonoids. In addition, the preparation contains a fructo-oligosaccharide with a prebiotic effect, such as inulin. The phyto-oestrogen of the preparation is intended to act on menopause symptoms in women, and the purpose of fructooligosaccharide is to enhance intestinal activity by increasing the growth of <i>Bifidobacteria</i> in the intestines, thus promoting phyto-oestrogen conversion and absorption in the intestines. In accordance with the invention, the preparation is a mixture of components in the form of a solid, finely divided powder and groats, such as a mixture consisting of soya flour, crushed flaxseed, fructooligosaccharide and a flavouring and colouring vegetal substance, such as dried rosehip or lingonberry, and which can be mixed as such in a liquid to form a drink.		

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## Functional food prepareate

This invention relates to a functional food preparation, which is based mainly on vegetal ingredients and is particularly intended to alleviate problems related with menopause in women.

The chief feature of the functional food preparation of the invention is the combination of fructooligosaccharides and vegetal phyto-oestrogens of various types in the same product, which is easy to use as a food supplement.

Fructooligosaccharides are chain-like carbohydrates consisting of a chain formed of fructosyl units with a glucosyl at the end, or of a fructosyl chain alone. By the chain length, i.e. the number of fructosyl units, fructooligosaccharides are divided into oligofructoses having a shorter chain, of which 1-kestose and nystose can be given as examples, an inulin having a longer chain (a common designation for fructooligosaccharides, which may contain up to 60 fructosyl units). Many cultivated vegetables, such as sugar-beet, chicory, Jerusalem artichoke, asparagus, onion, garlic, banana and tomato, contain fructooligosaccharides in abundance, however, fructooligosaccharides can also be produced synthetically.

Fructooligosaccharides are known to have a prebiotic effect, which means that they enhance selectively the growth of useful *Bifidobacteria* and *Lactobacilli* which produce acid in the intestines. Fructooligosaccharides also reduce the pH in the intestines, thus inhibiting the growth of pathogenetic bacteria and maintaining optimal bacterial balance for human health. Other known effects of fructooligosaccharides on humans is an increase in excrements and a decrease in blood fat values and cholesterol level.

Since digestive enzymes such as alpha-amylase, sucrase and maltase are not capable of decomposing fructooligosaccharides to any notable extent, and only the specific types of bacteria mentioned above utilise them selectively, fructooligosaccharides have been used as low-calorie sweetening agents in foodstuffs. However, owing to the prebiotic and other useful effects mentioned above, fructooligosaccharides have a potential of being used more extensively especially as a food supplement to enhance intestinal activity.

JP Patent Application 60133852, filed on 17 July 1985, describes a fermented soybean product with a caseous consistency, a "natto product", to which fructo-

oligosaccharide has been added and which is said to be health promoting in accelerating the growth of *Bifidobacteria* in the intestines. A similar product made of soya milk and containing added fructooligosaccharide has also been described in JP Patent Application 62036158, filed on 17 February 1987.

- 5 JP Patent Application 2295462, filed on 6 December 1990, also discloses a vegetal ceraceous product, to which fructooligosaccharide has been added and which is said to promote metabolism and to prevent diseases, and JP Patent Application 63063366, filed on 19 March 1988, discloses a vegetable dessert paste which contains fructooligosaccharide and is used to cure intestinal problems and  
10 constipation.

Soya has the characteristic of containing phyto-oestrogens in abundance, more specifically daidzein and genistein, belonging to the isoflavonoids. Phyto-oestrogens are hormone-like compounds occurring naturally in certain plants and greatly resembling the oestrogens produced by the female organism. It is known that  
15 vegetal phyto-oestrogens are converted in the intestines by the fermentation maintained by intestinal bacteria into substances having a similar effect as that of the oestrogens produced by the human organism. Thus, it is possible to alleviate problems connected with the menopause in women by adding phyto-oestrogens to the food, substituting these for synthetic oestrogen drugs. As a matter of fact, in  
20 countries where the food traditionally contains soybean products in abundance, women have significantly less menopause symptoms than in countries where the food is poor in phyto-oestrogens. Phyto-oestrogens prevent "hot flushes", prevent vaginal dryness and have also been confirmed to have an anti-depressive effect. Phyto-oestrogens also delay bone fragility, thus reducing the risk of contracting  
25 osteoporosis.

Except in soya, there is an abundance of phyto-oestrogens in flaxseed, which contains secoisolariciresinol and matairesinol belonging to lignans. In addition, many other plants, such as some cereal crops contain phyto-oestrogen in minor concentrations.

- 30 Owing to the known effects of phyto-oestrogens mentioned above, there is an abundance of functional food preparations on the market, in which especially soya, but also flaxseed constitute a chief ingredient. One typical such preparation consists of vegetal ingredients in the form of a finely or coarsely divided powder which contains soya flour or crushed flaxseed, or preferably both, and which is intended  
35 for use as a drink mixed in a liquid. Such a particulate preparation can also be used

as a supplement to be mixed in other foodstuffs, such as yoghurt and various cereals and flakes. Besides phyto-oestrogens, the preparation is rich in fibres and poly-unsaturated fatty acids, thus allowing the need for synthetic oestrogen drugs to be avoided during the menopause.

- 5 The purpose of this invention is to provide a functional food preparation combining the beneficial effects of fructooligosaccharides and vegetal phyto-oestrogen.

In this conjunction, the invention aims at the joint effect of fructooligosaccharides and phyto-oestrogens of various types simultaneously obtained in the human organism with one and the same food preparation, so that the growth especially of  
10 the useful *Bifidobacteria* in the intestines enhances the intestinal activity and thus boosts the conversion of phyto-oestrogens into a form usable by the intestines and their absorption into the human body. Moreover, a special purpose of the invention is to provide a preparation which is easy to use as a food supplement, mixed in various foodstuffs or drinks. Thus, the preparation of the invention is characterised  
15 by being a mixture of components in the form of solid, finely divided particles, which contains fructooligosaccharide with a prebiotic effect combined with a vegetal substance containing phyto-oestrogens, which consists of soya flour containing flavonoids and crushed flaxseed containing lignan.

The phyto-oestrogens contained in the vegetal ingredients of the preparation in  
20 accordance with the invention, i.e. the lignans contained in flaxseed and the flavonoids contained in soya, are clearly different, the components being thus complementary in increasing the spectrum of different phyto-oestrogens in the preparation and boosting their action, compared to a preparation containing phyto-oestrogens of one single type. The crushing of the flaxseed is indispensable in order  
25 to break the husks and to release lignans for use by the digestive system.

The preparation of the invention can be prepared in a manner known *per se* forming a mixture consisting of vegetal components, which can be mixed for instance in water, sour milk or juice, forming a drink consumed as such. With the adequate use of crushed flaxseed containing lignans and soya flour containing isoflavonoids, the  
30 phyto-oestrogen concentration of the preparation can be controlled within the range from approx. 0.05 to 0.6% by weight, preferably approx. 0.01 to 0.4% by weight. Other vegetal flavouring and colouring ingredients, preferably containing vitamins and minerals, such as dried rosehip or lingonberry can be further added to the preparation. Besides vegetal ingredients, fructooligosaccharide, such as e.g. inulin,  
35 is included in the preparation, preferably in a ratio of approx. 5 to 30% by weight

and most preferably approx. 10 to 20% by weight. These concentrations have been selected so that a daily intake of the preparation meets the daily need, which is estimated at approx. 1 to 10 g/day, preferably 2.5 to 10 g/day. Powdery inulin can be obtained for instance by extracting sugar-beet or chicory.

- 5 In accordance with the invention, other preferred foodstuffs are mixtures of finely divided vegetal components, consisting of 50 to 60% by weight of soya flour, 15 to 30% by weight of crushed flaxseed, 15 to 25% by weight of dried rosehip or lingonberry and 10 to 20% by weight of fructooligosaccharide.

10 The invention is explained in greater detail below with the aid of a number of exemplifying compositions of the food preparation in accordance with the invention.

#### Example 1

	Lecithinised soya flour	54%
	Dried rosehip	20%
15	Crushed flaxseed	16%
	Inulin/Frutafit®	10%

#### Example 2

	Low-fat soya flour	40%
20	Inulin/ Frutafit®	15%
	Rosehip	15%
	Full-fat soya flour	10%
	Crushed flaxseed	10%
	Dried lingonberry powder	5%
25	Canderel sweetener	5%

#### Example 3

	Low-fat soya flour	50%
	Rosehip	13%
30	Crushed flaxseed	10%
	Fibrex sugar-beet flakes	10%
	Raw cane sugar	10%
	Inulin/ Frutafit®	7%

**Example 4**

	Lecithinised soya flour	45%
	Crushed flaxseed	16%
	Fructooligosaccharide/Actilight®	15%
5	Dried lingonberry powder	12%
	Canderel sweetener	12%

**Example 5**

	Lecithinised soya flour	52%
10	Carob powder	14%
	Crushed flaxseed	13%
	Fructooligosaccharides/Actilight®	11%
	Raw cane sugar	10%

**15 Product data on the mixture components used:****Lecithinised soya flour**

- preheated
- colour: from yellowish to light brown
- granulation: min. 95% through #325 mesh US St.Sieve (0.045)
- 20 - fat content 8% (lecithin)
- protein content: 49% of the dry substance
- energy content: 1600kJ/100 g
- highly miscible with liquids

**25 Full-fat soya flour**

- preheated
- energy content 1880 kJ/100 g
- protein content min. 36% of the dry substance
- fat content min. 18% of the dry substance
- 30 - fibre content min. 3% of the dry substance
- trypsin inhibitors: max. 10.0 TIU/mg
- colour: light yellow
- granulation: less than 0.67 mm, 95%

**Low-fat soya flour**

- preheated
- energy content 1591 kJ/100 g
- protein content min. 47%
- 5 - fat content max. 2.0%
- fibre content max. 3%
- trypsin inhibitors: max. 10.0 TIU/mg
- colour: light yellow
- granulation: less than 0.075 mm

10

**Lingonberry powder**

- dried
- a strong taste of lingonberry

15 **Canderel sweetener**

- an aspartame-based sweetener
- aspartame content 3%
- a light powder
- colour: white
- 20 - sweetness value: the sweetness of 1 dl equals 1 dl of ordinary sugar
- energy content: 410 kcal/100 g, 40 kcal/1 dl

**Dried rosehip**

- prepared from mature rosehips, from which the interior seeds have been removed.
- 25 The berries have been rapidly dried using hot-air drying, resulting in optimal conservation of the vitamin C concentration.

**Crushed flaxseed**

- prepared from flaxseed from which the major portion of the oil has been removed
- 30 (defatted)
- fat content 17%
- protein content 30%
- fibre content 32%

35 **Inulin**

- trade name: Frutafit®
- separated from fresh chicory roots
- a white powder

- colour: white
- pH: neutral
- particle size  $20 < 80\% < 130 \mu\text{m}$
- solubility: excellent
- 5 - dry matter content:  $\geq 96\%$
- carbohydrate content of dry substance  $\geq 99.0\%$   
of which inulin  $\geq 90.0\%$  and  
monosaccharides and disaccharides  $\leq 10\%$
- 10 **Fructooligosaccharide**
  - trade name: Actilight®
  - separated from sugar-beet
  - powdery
  - fructooligosaccharide content 95%
- 15 - energy content: 200 kcal/100 g

**Fibre sugar-beet flakes**

- a flaky structure resembling rye flakes
- prepared from sugar-beet by physical means
- 20 - fibre content: 73%
- fibre: 1/3 water-soluble, gelling
- energy content: 225 kJ/100 g
- protein content: 10%
- pH  $4.5 \pm 0.5$
- 25 - particle size: 0.5-2.0 mm

**Raw sugar cane**

- prepared by crystallising pressed sugar cane juice
- contains minerals such as iron and calcium
- 30 - colour: brown
- crystal: coarser than that of brown sugar, for instance
- dissolution time of 10 minutes in a cold drink

It is obvious to those skilled in the art that the embodiments of the invention are not confined to the examples given above, but may vary within the scope of the

35 accompanying claims.

### Claims

1. A functional food preparation, characterised in that it is a mixture of components in the form of solid, finely divided particles, containing fructooligosaccharide with a prebiotic effect combined with a vegetal substance containing phyto-oestrogen, which consists of soya flour containing flavonoids and crushed flaxseed containing lignan.
2. A preparation as claimed in claim 1, characterised in that the fructooligosaccharides account for approx. 5 to 30% by weight, preferably approx. 10 to 20% by weight of the preparation.
3. A preparation as claimed in claim 1 or 2, characterised in that the fructooligosaccharide is inulin.
4. A preparation as claimed in any of the preceding claims, characterised in that the phyto-oestrogens account for approx. 0.05 to 0.6% by weight, preferably approx. 0.1 to 0.4% by weight of the preparation.
5. A preparation as claimed in any of the preceding claims, characterised in that it contains dried rosehip or lingonberry.
6. A preparation as claimed in claim 5, characterised in that it contains 50 to 60% by weight of soya flour, 15 to 30% by weight of crushed flaxseed, 15 to 25% by weight of dried rosehip or lingonberry and 10 to 20% by weight of fructooligosaccharide.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 98/00605

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A23L 1/09, A23L 1/308, A61K 31/715, A61K 31/56, A61K 35/78  
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61K, A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9603150 A1 (THE UNIVERSITY OF MONTANA), 8 February 1996 (08.02.96), page 5, line 11 - line 16; page 5, line 28 - page 6, line 1; page 6, line 25 - page 7, line 2, claims  --	1-6
Y	WO 9323069 A1 (KELLY, GRAHAM EDMUND), 25 November 1993 (25.11.93), page 2, line 12 - line 20; page 8, line 5 - line 18, claim 4, abstract  --	1-6
Y	WPI/Derwent's abstract, No 91-031795, week 9105, ABSTRACT OF JP2295462 (NAKAMURA T), 6 December 1990 (06.12.90), abstract  --	1-6



Further documents are listed in the continuation of Box C.



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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WPI/Derwent's abstract, No 89-035952, week 8925, ABSTRACT OF JP, 633091183 (ICHIMARU PHARCOS INC), 16 December 1988 (16.12.88), abstract  --	1-6
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**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

03/11/98

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